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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,569	06/25/2001	Maurice M. Moloney	9369-183	8071

7590 12/17/2002

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/087,569	Applicant(s)	McLoney et al
Examiner	FOX	Group Art Unit	1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

-3-

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

10/23/02

Responsive to communication(s) filed on _____.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 17-18, 20, 23-29 is/are pending in the application.

Of the above claim(s) 26-29 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 17-18, 20, 23-25 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). 7 Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

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Applicant's election without traverse of Group I in Paper No. 9 is acknowledged.

The effective filing date of the instantly claimed invention is 25 April 1997, the filing date of parent application Serial No. 08/846,021, now U.S. Patent 5,948,682, which was the first parent application to disclose a somatotropin gene and plant transformation therewith for production of the protein in the seed (see Example 13 of that application).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite in its recitation in line 2 of "obtained from the group of plants comprising" which employs improper Markush terminology. Replacement of the phrase with -- from a plant selected from the group consisting of-- would obviate this rejection. See MPEP 2173.05(h).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 17, 20 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 241,963 (LEDOUX).

The claims are broadly drawn to any plant seed which comprises a recombinantly expressed somatotropin (a synonym for growth hormone).

LEDOUX teaches transformed barley seeds which express human growth hormone (see, e.g., English translation of Abstract).

Claims 17-18, 20 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/13993 (UPJOHN).

The claims are broadly drawn to dicotyledonous plant seeds which recombinantly express a protein comprising a somatotropin, optionally in the form of a fusion protein.

UPJOHN teaches tobacco plant seeds comprising a construct comprising seed-specific promoters from seed storage protein genes of soybean, maize or common bean ligated to the bovine somatotropin (Bst) coding sequence, said Bst coding sequence optionally ligated to a portion of the plant seed storage protein-encoding sequence, for high levels of somatotropin production and its stable maintenance (see, e.g., page 1, top paragraph; page 5, line 26 through page 7, line 7; page 9, line 28 through page 12, line 19; page 13, line 12 through page 15, line 14; page 17, line 29 through page 21, line 19; pages 44-47 and claims 1-20).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-18, 20 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/13993 (UPJOHN) in view of Vandekerckhove et al.

The claims are broadly drawn to monocotyledonous or dicotyledonous plants such as rapeseed (*Brassica*) which have been transformed with a construct encoding a fusion protein comprising somatotropin, said fusion protein being expressed in the seed.

UPJOHN teaches dicotyledonous plants expressing a fusion protein comprising somatotropin and a portion of the plant seed storage protein gene, ligated to a seed-specific promoter from a seed storage protein gene, as discussed above, and suggests a variety of dicotyledonous plants including those grown for their seed (see, e.g., page 6, lines 27-31) for the production of pharmaceutical proteins (see, e.g., page 1, lines 15-18), but does not explicitly teach rapeseed plants or seeds.

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Vandekerckhove et al teach the production of high levels of an animal pharmaceutical peptide in seeds of rapeseed plants which have been transformed with a construct comprising an *Arabidopsis* seed storage protein gene promoter, which *Arabidopsis* is closely related to *Brassica*, a portion of the *Arabidopsis* seed storage protein-encoding sequence, and the animal peptide-encoding sequence ligated thereto, wherein the protein was stable and abundantly produced; and suggests the technique for the production of any pharmaceutically active protein including long peptides (see, e.g., page 929; page 930, column 1, bottom two paragraphs and Figure 1; page 931, column 1, bottom two paragraphs; page 932, column 1, top paragraph).

It would have been obvious to one of ordinary skill in the art to utilize the method of producing high levels of pharmaceutically active peptides such as somatotropin in plant seeds transformed with a fusion protein-encoding sequence ligated to a seed-specific promoter from a seed protein storage gene as taught by UPJOHN, and to modify that method by incorporating the *Brassica* transformation (and optionally the *Arabidopsis* seed storage protein gene promoter and portion of the coding sequence) taught by Vandekerckhove et al; given the high levels of successful protein production in the seed by Vandekerckhove et al, the suggestion by both references of the broad applicability of the technique regarding plant host and pharmaceutical protein to be produced, and the suggestion by UPJOHN that any dicotyledonous crop grown for its seed could be used.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 15, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

A handwritten signature in black ink, appearing to read "David T. Fox".